

REMARKS

Claims 1-75 are pending in this application. Claims 4-10, 14-20, 24-30, 34-60 and 72-73 are canceled herein without prejudice. Claims 1-3, 21-23, 61, 66, 74 and 75 are amended herein for clarity and to more particularly define the invention and are not narrowing amendments. Support for these amendments is found in the language of the original claims and throughout the specification as set forth below. No new matter is added by these claim amendments and their entry is respectfully requested. In light of these amendments and the following remarks, applicants respectfully request reconsideration of this application and allowance of the pending claims to issue.

I. Rejection under 35 U.S.C. § 112, second paragraph

A. Claims 1-75 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite on the basis that the claims recite "an immunogenic fragment thereof" but that it is not clear what exactly the fragment encompasses and the Examiner inquires as to whether what is meant is an epitope.

Claims 1-3, 21-23, 61 and 66 are amended herein to recite "a fragment containing an epitope thereof" in lieu of "immunogenic fragment thereof." Support for these amendments is found throughout the specification and at least at page 6, lines 13-17, page 33, lines 23-25 and page 80, lines 12-15. Applicants believe that these amendments address this rejection by describing the immunogenic fragment as an epitope, as set forth by the Examiner. Thus, this rejection is believed to have been overcome and applicants respectfully request its withdrawal.

B. Claims 1-75 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being vague and indefinite in the recitation of "virus-like particles" because it is unclear if virus particles are encompassed in the meaning.

As recited in the claims and throughout the specification, the term "virus-like particle,"

when used in regard to a modification of a gag gene product of HIV, appears in the context of a modification of a *gag* gene of HIV to inhibit formation of retroviral-like particles containing the *gag* gene product, the formation of which is known to occur when the *gag* gene product of HIV is not modified. See for example, page 35, lines 6-7, wherein it is stated that "...the gag gene product or immunogenic fragment thereof is modified to inhibit formation of particles, e.g., virus-like particles, containing the gag gene product or the immunogenic fragment thereof." See also, page 36, lines 13-14, wherein it is stated that "...the gag gene product or immunogenic fragment thereof is modified to inhibit release of particles, such as virus like particles, containing the gag gene product, or immunogenic fragment thereof, from a cell." Thus, in the context in which the term "virus-like particles" is used in claims 1-3, 21-23 and 66, it would be clear to one of ordinary skill in the art that this term means retrovirus-like particles. This is distinguished from the term "virus particles" as used in claim 66, which is used to describe alphavirus replicon particles or replication-competent alphavirus particles. Where appropriate, claim 66 is amended herein to clarify this term by replacing "alphavirus particle" with alphavirus replicon particle." Thus, these terms are clear and definite as recited in the claimed invention and applicants respectfully request the withdrawal of this rejection.

II. Rejection under 35 U.S.C. § 112, first paragraph

The Office Action states that claims 16-20, 36-40, 46, 53, 58-60, 72, 73 and 75 are rejected under 35 U.S.C. § 112, first paragraph, on the basis that the specification, while enabling for a method of inducing an immune response, allegedly does not provide enablement for treating or preventing infection by HIV in a subject. Specifically, the Office Action states that applicants have not shown any evidence that inducing an immune response equates to treating or preventing infection by HIV in a subject and that it is established that such treatment or prevention in a human subject is not a believable finding, without undue experimentation, lacking any evidence to the contrary. The Office Action goes on to state that the vaccine claims are assumed to be directed to the prevention of the infection.

Although applicants do not agree with the Examiner's assessment that claims 16-20, 36-40,

46, 53, 58-60, 72, 73 and 75 are not enabled in the present application, these claims are canceled herein without prejudice in order to expedite prosecution of the pending claims to issue. Thus, this rejection has been mooted and applicants respectfully request its withdrawal.

III. Amendments to claims

Claims 2, 3, 21 and 23 are amended herein to delete the phrase ""wherein the nucleic acids are each contained within a separate alphavirus replicon particle." Support for this amendment can be found throughout the specification and at least on page 34 wherein it is stated on lines 8-10 that the nucleic acids of this invention can be present in a vector and on lines 24-27, wherein it is stated that "[i]n another embodiment of the invention, the nucleic acids of this invention can be present in a composition comprising a population of alphavirus replicon particles which comprise two or more distinct isolated nucleic acids of this invention and wherein the nucleic acids are each contained within a separate alphavirus replicon particle." Thus, the specification supports the embodiment of claims 2, 3 21 and 23 as amended herein without introducing new matter and applicants respectfully request entry of these amendments.

Claim 66 is amended herein to recite "propagation in lieu of "replication" to provide the correct technical term for this aspect of the invention. Support for this amendment is found, at least, in the specification on page 35, lines 14-15, wherein a "propagation-defective single cycle vector construct" is described and on page 68, lines 4-5, wherein it is stated that "[t]he vaccines of this invention are exemplified by the use of a propagation-defective, replicon particle vector system..." Thus, the specification supports this amendment without introducing new matter and applicants respectfully request entry of this amendment.

IV. Supplemental Information Disclosure Statement

A Supplemental Information Disclosure Statement is included herewith. Applicants respectfully request that the documents listed on the enclosed Form PTO 1449 be considered and officially made of record in this application.

Application Serial No. 09/991,258

Attorney Docket No. 9368.6IP

Page 12

The Examiner is invited and encouraged to contact the undersigned directly if such contact will expedite the prosecution of this application to issuance.

A check in the amount of \$590.00 is enclosed (\$410.00 fee for a two month extension of time and \$180.00 fee for submission of a supplemental Information Disclosure Statement under 37 C.F.R. § 1.97(c)). This amount is believed to be correct; however, the Commissioner is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-0220.

Respectfully submitted,



Mary L. Miller

Registration No. 39,303

USPTO Customer No. 20792

Myers Bigel Sibley & Sajovec, P.A.

Post Office Box 37428

Raleigh, NC 27627

Telephone (919) 854-1400

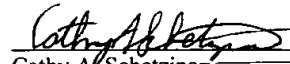
Facsimile (919) 854-1401

CERTIFICATE OF EXPRESS MAILING

"Express Mail" mailing label number: EV 353594794 US

Date of Deposit: December 1, 2003

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



Cathy A. Schetzina